

**ANNEX III**  
**LABELLING AND PACKAGE LEAFLET**

## **B. PACKAGE LEAFLET**

## PACKAGE LEAFLET

**Read all of this leaflet carefully before you start using this medicine.**

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.

### **In this leaflet:**

1. What PegIntron is and what it is used for
2. Before you use PegIntron
3. How to use PegIntron
4. Possible side effects
5. Storing PegIntron
6. Further information

**PegIntron** 50 micrograms powder and solvent for solution for injection  
peginterferon alfa-2b (conjugation of recombinant interferon alfa-2b with monomethoxy polyethylene glycol)

- The active substance is peginterferon alfa-2b, 50 micrograms/0.5 ml.
- The other ingredients are:  
Powder: dibasic sodium phosphate, monobasic sodium phosphate, sucrose and polysorbate 80;  
Solvent: water for injections 0.7 ml/ampoule.

Marketing Authorisation Holder: SP Europe, 73, rue de Stalle, B-1180 Bruxelles, Belgium

Manufacturer: SP (Brinny) Company, Innishannon, County Cork, Ireland

## **1. WHAT PEGINTRON IS AND WHAT IT IS USED FOR**

The pharmaceutical form is: powder and solvent for solution for injection.  
The powder is contained in a 2 ml vial and the solvent is presented in a 2 ml ampoule.

PegIntron 50 micrograms is available in different pack sizes:

- 1 vial of powder for solution for injection and 1 ampoule of solvent for parenteral use;
- 1 vial of powder for solution for injection, 1 ampoule of solvent for parenteral use, 1 injection syringe, 2 injection needles and 1 cleansing swab;
- 4 vials of powder for solution for injection and 4 ampoules of solvent for parenteral use;
- 4 vials of powder for solution for injection, 4 ampoules of solvent for parenteral use, 4 injection syringes, 8 injection needles and 4 cleansing swabs;
- 6 vials of powder for solution for injection and 6 ampoules of solvent for parenteral use;
- 12 vials of powder for solution for injection, 12 ampoules of solvent for parenteral use, 12 injection syringes, 24 injection needles and 12 cleansing swabs.

Not all pack sizes may be marketed.

Interferons modify the response of the body's immune system to help fight infections and severe diseases. PegIntron, which contains an interferon, is used for the treatment of chronic hepatitis C, a viral infection of the liver.

PegIntron is best used for this treatment in combination with ribavirin.

PegIntron is used alone in case of intolerance or contraindication to ribavirin.

## **2. BEFORE YOU USE PEGINTRON**

PegIntron is not recommended for use in patients under the age of 18 years.

### **Do not use PegIntron:**

- If you are hypersensitive (allergic) to peginterferon alfa-2b or any of the other ingredients of PegIntron.
- If you are hypersensitive (allergic) to any interferon.
- If you are pregnant or breast feeding.
- If you have had a severe nervous or mental disorder, especially if you have been very depressed or have thought about suicide, or tried to harm yourself.
- If you have had severe heart problems, or if you have heart disease that has not been well controlled during the past 6 months.
- If you have severe medical conditions that leave you very weak, including severe kidney disease.
- If you have autoimmune hepatitis or any other problem with your immune system; if you are taking medicine that suppresses your immune system (your immune system protects you against infection and some diseases).
- If you have advanced, uncontrolled liver disease (other than hepatitis C).
- If you have thyroid disease that is not well controlled with medicines.
- If you have a condition that causes convulsions (seizures, or “fits”).

### **Take special care with PegIntron:**

- If you develop symptoms of a severe allergic reaction (such as difficulty in breathing, wheezing, or hives) while on this medication, seek medical help immediately.
- If you ever had a heart attack or a heart problem.
- If you have ever been treated for depression or any other nervous or mental disorder.
- If you have had a problem with your liver (other than hepatitis C).
- If you develop symptoms associated with a cold or other respiratory infection, such as fever, cough, or any difficulty in breathing, tell your doctor.
- If you are diabetic, your doctor may ask you to have an eye examination.
- If you have had any serious illness affecting your breathing or your blood.
- If you have psoriasis, it may become worse while you are using PegIntron.
- If you are planning to become pregnant, discuss this with your doctor before starting to use PegIntron.

### **Pregnancy**

Ask your doctor or pharmacist for advice before taking any medicine. Do not use PegIntron during pregnancy. The effect on human pregnancy is not known.

### **Breast-feeding**

Ask your doctor or pharmacist for advice before taking any medicine. It is not known whether this product is present in human milk. Therefore, do not breast-feed an infant if you are taking PegIntron.

### **Driving and using machines:**

Do not drive or operate any tools or machines if you feel tired, sleepy or confused while taking PegIntron.

### **Using other medicines:**

Please inform your doctor or pharmacist if you are taking or have recently taken any other medicines, even those not prescribed.

## **3. HOW TO USE PEGINTRON**

Your doctor has prescribed PegIntron specifically for you and your current condition; do not share this medicine with anyone else.

Your doctor has determined your dose of PegIntron based on your weight. If necessary, the dose may be changed during treatment.

### **Combination treatment**

PegIntron, when given with ribavirin capsules, is usually given at a dose of 1.5 microgram/kg once a week.

Ribavirin capsules are taken every day, morning and evening. The number of ribavirin capsules you take depends on your weight.

- If you weigh less than 65 kg, take 2 capsules in the morning and 2 in the evening (total of 800 mg each day).
- If you weigh between 65 and 85 kg, take 2 capsules in the morning and 3 in the evening (total of 1,000 mg each day).
- If you weigh more than 85 kg, take 3 capsules in the morning and 3 in the evening (total 1,200 mg each day).

The combination treatment is continued for at least 6 months, and sometimes for one year.

### **PegIntron alone:**

PegIntron, when given alone, is usually given at a dose of 0.5 or 1.0 microgram/kg once a week, for at least 6 months, and possibly for 1 year.

### **All patients:**

If you are injecting PegIntron yourself, please be sure that the dose that has been prescribed for you is clearly provided on the package of medicine you receive.

If you have the impression that the effect of PegIntron is too strong or too weak, talk to your doctor or pharmacist.

PegIntron is intended for subcutaneous use. This means that it is injected through a short injection needle into the fatty tissue just under your skin. If you are injecting this medicine yourself, you will be instructed how to prepare and give the injection. Detailed instructions for subcutaneous administration are provided with this leaflet (see How to self-inject PegIntron at the end of the package leaflet).

Prepare the dose just before you intend to inject it and use it immediately. Look carefully at the reconstituted solution prior to administration. Do not use if discolouration of the reconstituted solution is present. Discard any solution that is left in the vial after you give yourself the injection.

Inject PegIntron once each week on the same day. Injecting it at the same time of day each week will help you not to forget to take it.

Use PegIntron exactly as prescribed by your doctor. Do not exceed the recommended dosage, and take it for as long as prescribed.

### **If you use more PegIntron than you should:**

Tell your doctor or healthcare professional as soon as possible.

### **If you forget to take PegIntron:**

Take the dose as soon as you remember, then continue your treatment as usual.

Do not take a double dose to make up for forgotten individual doses. Contact your doctor or pharmacist if needed.

## **4. POSSIBLE SIDE EFFECTS**

Like all medicines, PegIntron can have side effects. Although not all of these side effects may occur, they may need medical attention if they do.

Check with your doctor immediately if any of the following side effects occur: chest pain; changes in the way your heart beats; breathing problems, confusion; feeling depressed, wanting to harm yourself, numbness or tingling feeling; trouble sleeping, thinking or concentrating; severe stomach pain; fever or chills beginning after a few weeks of treatment, pain in your lower back or side; problems with your eyesight or hearing; severe bleeding from your nose; your doctor will test your blood to ensure that your white blood cell (cells that fight infection) count and platelets (blood clotting cells) are at acceptable levels.

The most common side effects with the combination of PegIntron and ribavirin capsules are irritation or redness at the site of injection, headache, tired feeling, shaking chills, fever, flu-like symptoms, weakness, loss of weight, nausea, loss of appetite, diarrhoea or loose stools, stomach pain, vomiting, muscle aches, pain in joints and muscles, feeling depressed, irritability, trouble falling asleep or staying asleep, feeling anxious or nervous, difficulty concentrating, mood swings, hair loss, itching, dry skin, sore throat, coughing, difficult breathing, dizziness, virus infection, rash, and dry mouth.

Other common side effects that may occur with combination treatment are increased sweating, chest pain, pain on the right side around your ribs, numbness or tingling feeling, change in thyroid gland activity (which may make you feel tired or, less commonly, energetic), constipation, stomach upset, rapid heart rate, agitation, nervousness, difficult or irregular menstrual period, stuffy or runny nose, change in taste, blurred vision.

Less common are pain at the place of injection, flushing, low or high blood pressure, dry or teary eyes, redness of skin or skin disorder, feeling unwell, feeling faint, confusion, increased or decreased sensitivity to touch, tense muscles, loss of interest in sex, shaky hands, vertigo (spinning feeling), intestinal gas (flatus), bleeding gums or sores in mouth, changes in hearing or ringing in ears, thirst, aggressive behaviour, feeling sleepy, fever blisters, fungal infections, irritation of prostate gland, ear or respiratory infections, sinusitis, abnormal hair texture, sensitivity to sunlight, migraine headache, eye pain or infection, and swollen glands.

Very rarely sarcoidosis (a disease characterised by persistent fever, weight loss, joint pain and swelling, skin lesions and swollen glands) has been reported. Check with your doctor immediately if you have any of these symptoms.

When PegIntron is used alone, some of these effects are less likely to occur, and some have not occurred at all.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

## **5. STORING PEGINTRON**

Keep out of the reach and sight of children.

Store at 2°C - 8°C (in a refrigerator).

Do not use after the expiry date stated on the carton.

After reconstitution, use the reconstituted solution immediately or within 24 hours when stored at 2°C - 8°C (in a refrigerator).

Do not use PegIntron if you notice discolouration of the powder.

## 6. FURTHER INFORMATION

For any information about this medicinal product, please contact the local representative of the Marketing Authorisation Holder.

### **België/Belgique/Belgien**

Rue de Stalle/Stallestraat 73  
B-1180 Bruxelles/Brussel/Brüssel  
Tél/Tel: + 32-(0)2 370 92 11

### **Luxembourg/Luxemburg**

Rue de Stalle 73  
B-1180 Bruxelles/Brüssel  
Belgique/Belgien  
Tél: + 32-(0)2 370 92 11

### **Danmark**

Hvedemarken 12  
DK-3520 Farum  
Tlf: + 45-44 39 50 00

### **Nederland**

Maarssenbroeksedijk 4  
NL-3542 DN Utrecht  
Tel: + 31-(0)30 240 88 88

### **Deutschland**

Thomas-Dehler-Straße 27  
D-81737 München  
Tel: + 49-(0)89 627 31-0

### **Norge**

Ankerveien 209  
N-1359 Eiksmarka  
Tlf: + 47 67 16 64 50

### **Ελλάδα**

Αγίου Δημητρίου 63  
GR-174 55 Άλιμος  
Τηλ: + 30-(0)10 98 97 300

### **Österreich**

Badener Strasse 23  
A-2514 Traiskirchen  
Tel: + 43-(0)2252 502-0

### **España**

Km. 36, Ctra. Nacional I  
E-28750 San Agustín de Guadalix - Madrid  
Tel: + 34-91 848 85 00

### **Portugal**

Casal do Colaride  
Aqualva  
P-2735 Cacém  
Tel: + 351-21 433 93 00

### **France**

92 rue Baudin  
F-92300 Levallois-Perret  
Tél: + 33-(0)1 41 06 35 00

### **Suomi/Finland**

PL 3/PB 3  
FIN-02201 Espoo/Esbo  
Puh/Tel: + 358-(0)9 613 55 51

### **Ísland**

Lynghálsi 13  
IS-110 Reykjavík  
Tel: + 354 540 80 00

### **Sverige**

Box 27190  
S-10252 Stockholm  
Tel: + 46-(0)8 522 21 500

### **Ireland**

Shire Park  
Welwyn Garden City  
Hertfordshire AL7 1TW - UK  
United Kingdom  
Tel: + 44-(0)1 707 363 636

### **United Kingdom**

Shire Park  
Welwyn Garden City  
Hertfordshire AL7 1TW - UK  
Tel: + 44-(0)1 707 363 636

### **Italia**

Centro Direzionale Milano Due  
Palazzo Borromini  
I-20090 Segrate (Milano)  
Tel: + 39-02 21018.1

**This leaflet was last approved on**

## HOW TO SELF-INJECT PEGINTRON?

The following instructions explain how to inject PegIntron yourself. Please read the instructions carefully and follow them step by step. Your doctor or his/her assistant will instruct you how to self-inject PegIntron. Do not attempt to inject yourself unless you are sure you understand the procedure and requirement of self-injection.

### Preparation

Collect necessary items before you begin:

- a vial of PegIntron powder for injection;
- an ampoule of solvent for PegIntron (water for injections);
- a 1 ml syringe;
- a long needle (for example  $0.8 \times 40$  mm [21 gauge 1.5 inch]) to be used to add water for injections to the PegIntron powder vial;
- a short needle (for example  $0.3 \times 13$  mm [30 gauge 0.5 inch]) for the subcutaneous injection;
- a cleansing swab.

Wash your hands carefully.

### Reconstituting PegIntron powder for injection

Before reconstitution, PegIntron may appear either as a white, tablet-shaped solid that is whole or in pieces, or as a white powder.

Remove the protective cap from the PegIntron vial. Clean the rubber top of the vial with a cleansing swab. You can save the swab to clean the skin area where you will inject the dose. Remove the syringe from the wrapping. Do not touch the tip of the syringe. Take the long needle and place it firmly on to the tip of the syringe. Remove the needle guard without touching the needle and keep the syringe with the needle in your hand. Tap the top of the ampoule of solvent gently to make sure that all the liquid is at the bottom of the ampoule. Break off the top of the ampoule of solvent. Insert the needle in the ampoule of solvent and withdraw the total amount of solvent.

When the total amount of solvent is combined with the full amount of PegIntron powder, the solution will be at the correct concentration to measure your dose (i.e., the labelled amount is contained in 0.5 ml).

A small volume is lost during preparation of PegIntron for injection and when the dose is measured and injected. Therefore, each vial contains an excess amount of solvent and PegIntron powder to ensure delivery of the labelled dose in 0.5 ml of PegIntron, solution for injection.

To prepare the PegIntron solution, insert the needle through the rubber top of the PegIntron vial and gently place the needle tip against the glass wall of the vial without touching the cleaned top of the vial with your hands.

Inject the solvent **SLOWLY**, aiming the stream of liquid at the glass wall of the vial. It is best not to aim the stream directly at the white solid or powder, or to inject the liquid quickly, as this causes a greater amount of bubbles. The solution may appear cloudy or bubbly for a few minutes. This is to be expected and is not cause for concern.

To dissolve the entire contents, swirl the PegIntron vial with a gentle rotary motion leaving the needle and attached syringe in the vial. **Do not shake**, but gently turn the vial upside down until any powder at the top of the vial is dissolved. The contents should now be completely dissolved. Stand the vial upright and let any bubbles present in the solution rise to the top of the solution. Once the solution has settled and all bubbles have risen to the top of the solution, you should have a clear solution with a small ring of tiny bubbles around the top. Now you can withdraw your dose from the vial. Use this solution immediately. If it cannot be used immediately, the solution may be refrigerated for up to 24 hours.

### Measuring the dose of PegIntron from the reconstituted powder for injection

Turn the vial and the syringe upside down in one hand. Be sure the tip of needle is in the PegIntron reconstituted solution. Your other hand will be free to move the plunger. Pull back on the plunger



slowly to draw just more than the dose prescribed by your doctor into the syringe. Hold the syringe with the needle in the vial pointing up, remove the syringe from the long needle leaving the needle in the vial and without touching the tip of the syringe. Take the short needle and place it firmly on to the tip of the syringe. Remove the needle guard from the syringe needle and check for air bubbles in the syringe. If you see any bubbles, pull the plunger slightly back; tap the syringe gently, with the needle pointing upwards, until the bubbles disappear. Push up the plunger slowly back to the correct dose. Replace the needle guard and place the syringe with the needle on a flat surface.

Be sure the solution is at room temperature up to 25°C. If the solution is cold, warm the syringe between your palms. Inspect visually the reconstituted solution prior to administration: do not use if discolouration or particulate matter is present. You are now ready to inject the dose.

#### Injecting the solution

Select the injection site. The best sites for injection are tissues with a layer of fat between skin and muscle: thigh, outer surface of the upper arm (you may need the assistance of another person to use this site), abdomen (except the navel or waistline). If you are exceptionally thin, use only the thigh or outer surface of the arm for injection.

#### **Change your injection site each time.**

Cleanse and disinfect the skin where the injection is to be made. Wait for the area to dry. Remove the needle guard. With one hand, pinch a fold of loose skin. With your other hand, hold the syringe as you would a pencil. Insert the needle into the pinched skin at an angle of approximately 45°. After the needle is in, remove the hand used to pinch the skin and use it to hold the syringe barrel. Pull back the plunger very slightly with one hand. If blood comes into the syringe, the needle has entered a blood vessel. Do not inject into this site; withdraw the needle and repeat the procedure. Inject the solution by pushing the plunger all the way down gently.

Pull the needle straight out of the skin. Press the injection site with a small bandage or sterile gauze if necessary for several seconds. Do not massage the injection site. If there is bleeding, cover with an adhesive bandage.

The vial, ampoule and injection materials intended for single use must be discarded. Dispose of the syringe and needles safely in a closed container.

## PACKAGE LEAFLET

**Read all of this leaflet carefully before you start using this medicine.**

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.

### **In this leaflet:**

1. What PegIntron is and what it is used for
2. Before you use PegIntron
3. How to use PegIntron
4. Possible side effects
5. Storing PegIntron
6. Further information

**PegIntron** 80 micrograms powder and solvent for solution for injection  
peginterferon alfa-2b (conjugation of recombinant interferon alfa-2b with monomethoxy polyethylene glycol)

- The active substance is peginterferon alfa-2b, 80 micrograms/0.5 ml.
- The other ingredients are:  
Powder: dibasic sodium phosphate, monobasic sodium phosphate, sucrose and polysorbate 80;  
Solvent: water for injections 0.7 ml/ampoule.

Marketing Authorisation Holder: SP Europe, 73, rue de Stalle, B-1180 Bruxelles, Belgium

Manufacturer: SP (Brinny) Company, Innishannon, County Cork, Ireland

## **1. WHAT PEGINTRON IS AND WHAT IT IS USED FOR**

The pharmaceutical form is: powder and solvent for solution for injection.

The powder is contained in a 2 ml vial and the solvent is presented in a 2 ml ampoule.

PegIntron 80 micrograms is available in different pack sizes:

- 1 vial of powder for solution for injection and 1 ampoule of solvent for parenteral use;
- 1 vial of powder for solution for injection, 1 ampoule of solvent for parenteral use, 1 injection syringe, 2 injection needles and 1 cleansing swab;
- 4 vials of powder for solution for injection and 4 ampoules of solvent for parenteral use;
- 4 vials of powder for solution for injection, 4 ampoules of solvent for parenteral use, 4 injection syringes, 8 injection needles and 4 cleansing swabs;
- 6 vials of powder for solution for injection and 6 ampoules of solvent for parenteral use;
- 12 vials of powder for solution for injection, 12 ampoules of solvent for parenteral use, 12 injection syringes, 24 injection needles and 12 cleansing swabs.

Not all pack sizes may be marketed.

Interferons modify the response of the body's immune system to help fight infections and severe diseases. PegIntron, which contains an interferon, is used for the treatment of chronic hepatitis C, a viral infection of the liver.

PegIntron is best used for this treatment in combination with ribavirin.

PegIntron is used alone in case of intolerance or contraindication to ribavirin.

## **2. BEFORE YOU USE PEGINTRON**

PegIntron is not recommended for use in patients under the age of 18 years.

### **Do not use PegIntron:**

- If you are hypersensitive (allergic) to peginterferon alfa-2b or any of the other ingredients of PegIntron.
- If you are hypersensitive (allergic) to any interferon.
- If you are pregnant or breast feeding.
- If you have had a severe nervous or mental disorder, especially if you have been very depressed or have thought about suicide, or tried to harm yourself.
- If you have had severe heart problems, or if you have heart disease that has not been well controlled during the past 6 months.
- If you have severe medical conditions that leave you very weak, including severe kidney disease.
- If you have autoimmune hepatitis or any other problem with your immune system; if you are taking medicine that suppresses your immune system (your immune system protects you against infection and some diseases).
- If you have advanced, uncontrolled liver disease (other than hepatitis C).
- If you have thyroid disease that is not well controlled with medicines.
- If you have a condition that causes convulsions (seizures, or “fits”).

### **Take special care with PegIntron:**

- If you develop symptoms of a severe allergic reaction (such as difficulty in breathing, wheezing, or hives) while on this medication, seek medical help immediately.
- If you ever had a heart attack or a heart problem.
- If you have ever been treated for depression or any other nervous or mental disorder.
- If you have had a problem with your liver (other than hepatitis C).
- If you develop symptoms associated with a cold or other respiratory infection, such as fever, cough, or any difficulty in breathing, tell your doctor.
- If you are diabetic, your doctor may ask you to have an eye examination.
- If you have had any serious illness affecting your breathing or your blood.
- If you have psoriasis, it may become worse while you are using PegIntron.
- If you are planning to become pregnant, discuss this with your doctor before starting to use PegIntron.

### **Pregnancy**

Ask your doctor or pharmacist for advice before taking any medicine. Do not use PegIntron during pregnancy. The effect on human pregnancy is not known.

### **Breast-feeding**

Ask your doctor or pharmacist for advice before taking any medicine. It is not known whether this product is present in human milk. Therefore, do not breast-feed an infant if you are taking PegIntron.

### **Driving and using machines:**

Do not drive or operate any tools or machines if you feel tired, sleepy or confused while taking PegIntron.

### **Using other medicines:**

Please inform your doctor or pharmacist if you are taking or have recently taken any other medicines, even those not prescribed.

## **3. HOW TO USE PEGINTRON**

Your doctor has prescribed PegIntron specifically for you and your current condition; do not share this medicine with anyone else.

Your doctor has determined your dose of PegIntron based on your weight. If necessary, the dose may be changed during treatment.

**Combination treatment**

PegIntron, when given with ribavirin capsules, is usually given at a dose of 1.5 microgram/kg once a week.

Ribavirin capsules are taken every day, morning and evening. The number of ribavirin capsules you take depends on your weight.

- If you weigh less than 65 kg, take 2 capsules in the morning and 2 in the evening (total of 800 mg each day).
- If you weigh between 65 and 85 kg, take 2 capsules in the morning and 3 in the evening (total of 1,000 mg each day).
- If you weigh more than 85 kg, take 3 capsules in the morning and 3 in the evening (total 1,200 mg each day).

The combination treatment is continued for at least 6 months, and sometimes for one year.

**PegIntron alone:**

PegIntron, when given alone, is usually given at a dose of 0.5 or 1.0 microgram/kg once a week, for at least 6 months, and possibly for 1 year.

**All patients:**

If you are injecting PegIntron yourself, please be sure that the dose that has been prescribed for you is clearly provided on the package of medicine you receive.

If you have the impression that the effect of PegIntron is too strong or too weak, talk to your doctor or pharmacist.

PegIntron is intended for subcutaneous use. This means that it is injected through a short injection needle into the fatty tissue just under your skin. If you are injecting this medicine yourself, you will be instructed how to prepare and give the injection. Detailed instructions for subcutaneous administration are provided with this leaflet (see How to self-inject PegIntron at the end of the package leaflet).

Prepare the dose just before you intend to inject it and use it immediately. Look carefully at the reconstituted solution prior to administration. Do not use if discolouration of the reconstituted solution is present. Discard any solution that is left in the vial after you give yourself the injection.

Inject PegIntron once each week on the same day. Injecting it at the same time of day each week will help you not to forget to take it.

Use PegIntron exactly as prescribed by your doctor. Do not exceed the recommended dosage, and take it for as long as prescribed.

**If you use more PegIntron than you should:**

Tell your doctor or healthcare professional as soon as possible.

**If you forget to take PegIntron:**

Take the dose as soon as you remember, then continue your treatment as usual.

Do not take a double dose to make up for forgotten individual doses. Contact your doctor or pharmacist if needed.

#### **4. POSSIBLE SIDE EFFECTS**

Like all medicines, PegIntron can have side effects. Although not all of these side effects may occur, they may need medical attention if they do.

Check with your doctor immediately if any of the following side effects occur: chest pain; changes in the way your heart beats; breathing problems, confusion; feeling depressed, wanting to harm yourself, numbness or tingling feeling; trouble sleeping, thinking or concentrating; severe stomach pain; fever or chills beginning after a few weeks of treatment, pain in your lower back or side; problems with your eyesight or hearing; severe bleeding from your nose; your doctor will test your blood to ensure that your white blood cell (cells that fight infection) count and platelets (blood clotting cells) are at acceptable levels.

The most common side effects with the combination of PegIntron and ribavirin capsules are irritation or redness at the site of injection, headache, tired feeling, shaking chills, fever, flu-like symptoms, weakness, loss of weight, nausea, loss of appetite, diarrhoea or loose stools, stomach pain, vomiting, muscle aches, pain in joints and muscles, feeling depressed, irritability, trouble falling asleep or staying asleep, feeling anxious or nervous, difficulty concentrating, mood swings, hair loss, itching, dry skin, sore throat, coughing, difficult breathing, dizziness, virus infection, rash, and dry mouth.

Other common side effects that may occur with combination treatment are increased sweating, chest pain, pain on the right side around your ribs, numbness or tingling feeling, change in thyroid gland activity (which may make you feel tired or, less commonly, energetic), constipation, stomach upset, rapid heart rate, agitation, nervousness, difficult or irregular menstrual period, stuffy or runny nose, change in taste, blurred vision.

Less common are pain at the place of injection, flushing, low or high blood pressure, dry or teary eyes, redness of skin or skin disorder, feeling unwell, feeling faint, confusion, increased or decreased sensitivity to touch, tense muscles, loss of interest in sex, shaky hands, vertigo (spinning feeling), intestinal gas (flatus), bleeding gums or sores in mouth, changes in hearing or ringing in ears, thirst, aggressive behaviour, feeling sleepy, fever blisters, fungal infections, irritation of prostate gland, ear or respiratory infections, sinusitis, abnormal hair texture, sensitivity to sunlight, migraine headache, eye pain or infection, and swollen glands.

Very rarely sarcoidosis (a disease characterised by persistent fever, weight loss, joint pain and swelling, skin lesions and swollen glands) has been reported. Check with your doctor immediately if you have any of these symptoms.

When PegIntron is used alone, some of these effects are less likely to occur, and some have not occurred at all.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

#### **5. STORING PEGINTRON**

Keep out of the reach and sight of children.

Store at 2°C - 8°C (in a refrigerator).

Do not use after the expiry date stated on the carton.

After reconstitution, use the reconstituted solution immediately or within 24 hours when stored at 2°C - 8°C (in a refrigerator).

Do not use PegIntron if you notice discolouration of the powder.

## 6. FURTHER INFORMATION

For any information about this medicinal product, please contact the local representative of the Marketing Authorisation Holder.

### **België/Belgique/Belgien**

Rue de Stalle/Stallestraat 73  
B-1180 Bruxelles/Brussel/Brüssel  
Tél/Tel: + 32-(0)2 370 92 11

### **Luxembourg/Luxemburg**

Rue de Stalle 73  
B-1180 Bruxelles/Brüssel  
Belgique/Belgien  
Tél: + 32-(0)2 370 92 11

### **Danmark**

Hvedemarken 12  
DK-3520 Farum  
Tlf: + 45-44 39 50 00

### **Nederland**

Maarssenbroeksedijk 4  
NL-3542 DN Utrecht  
Tel: + 31-(0)30 240 88 88

### **Deutschland**

Thomas-Dehler-Straße 27  
D-81737 München  
Tel: + 49-(0)89 627 31-0

### **Norge**

Ankerveien 209  
N-1359 Eiksmarka  
Tlf: + 47 67 16 64 50

### **Ελλάδα**

Αγίου Δημητρίου 63  
GR-174 55 Άλιμος  
Τηλ: + 30-(0)10 98 97 300

### **Österreich**

Badener Strasse 23  
A-2514 Traiskirchen  
Tel: + 43-(0)2252 502-0

### **España**

Km. 36, Ctra. Nacional I  
E-28750 San Agustín de Guadalix - Madrid  
Tel: + 34-91 848 85 00

### **Portugal**

Casal do Colaride  
Aqualva  
P-2735 Cacém  
Tel: + 351-21 433 93 00

### **France**

92 rue Baudin  
F-92300 Levallois-Perret  
Tél: + 33-(0)1 41 06 35 00

### **Suomi/Finland**

PL 3/PB 3  
FIN-02201 Espoo/Esbo  
Puh/Tel: + 358-(0)9 613 55 51

### **Ísland**

Lynghálsi 13  
IS-110 Reykjavík  
Tel: + 354 540 80 00

### **Sverige**

Box 27190  
S-10252 Stockholm  
Tel: + 46-(0)8 522 21 500

### **Ireland**

Shire Park  
Welwyn Garden City  
Hertfordshire AL7 1TW - UK  
United Kingdom  
Tel: + 44-(0)1 707 363 636

### **United Kingdom**

Shire Park  
Welwyn Garden City  
Hertfordshire AL7 1TW - UK  
Tel: + 44-(0)1 707 363 636

### **Italia**

Centro Direzionale Milano Due  
Palazzo Borromini  
I-20090 Segrate (Milano)  
Tel: + 39-02 21018.1

**This leaflet was last approved on**

## HOW TO SELF-INJECT PEGINTRON?

The following instructions explain how to inject PegIntron yourself. Please read the instructions carefully and follow them step by step. Your doctor or his/her assistant will instruct you how to self-inject PegIntron. Do not attempt to inject yourself unless you are sure you understand the procedure and requirement of self-injection.

### Preparation

Collect necessary items before you begin:

- a vial of PegIntron powder for injection;
- an ampoule of solvent for PegIntron (water for injections);
- a 1 ml syringe;
- a long needle (for example  $0.8 \times 40$  mm [21 gauge 1.5 inch]) to be used to add water for injections to the PegIntron powder vial;
- a short needle (for example  $0.3 \times 13$  mm [30 gauge 0.5 inch]) for the subcutaneous injection;
- a cleansing swab.

Wash your hands carefully.

### Reconstituting PegIntron powder for injection

Before reconstitution, PegIntron may appear either as a white, tablet-shaped solid that is whole or in pieces, or as a white powder.

Remove the protective cap from the PegIntron vial. Clean the rubber top of the vial with a cleansing swab. You can save the swab to clean the skin area where you will inject the dose. Remove the syringe from the wrapping. Do not touch the tip of the syringe. Take the long needle and place it firmly on to the tip of the syringe. Remove the needle guard without touching the needle and keep the syringe with the needle in your hand. Tap the top of the ampoule of solvent gently to make sure that all the liquid is at the bottom of the ampoule. Break off the top of the ampoule of solvent. Insert the needle in the ampoule of solvent and withdraw the total amount of solvent.

When the total amount of solvent is combined with the full amount of PegIntron powder, the solution will be at the correct concentration to measure your dose (i.e., the labelled amount is contained in 0.5 ml).

A small volume is lost during preparation of PegIntron for injection and when the dose is measured and injected. Therefore, each vial contains an excess amount of solvent and PegIntron powder to ensure delivery of the labelled dose in 0.5 ml of PegIntron, solution for injection.

To prepare the PegIntron solution, insert the needle through the rubber top of the PegIntron vial and gently place the needle tip against the glass wall of the vial without touching the cleaned top of the vial with your hands.

Inject the solvent **SLOWLY**, aiming the stream of liquid at the glass wall of the vial. It is best not to aim the stream directly at the white solid or powder, or to inject the liquid quickly, as this causes a greater amount of bubbles. The solution may appear cloudy or bubbly for a few minutes. This is to be expected and is not cause for concern.

To dissolve the entire contents, swirl the PegIntron vial with a gentle rotary motion leaving the needle and attached syringe in the vial. **Do not shake**, but gently turn the vial upside down until any powder at the top of the vial is dissolved. The contents should now be completely dissolved. Stand the vial upright and let any bubbles present in the solution rise to the top of the solution. Once the solution has settled and all bubbles have risen to the top of the solution, you should have a clear solution with a small ring of tiny bubbles around the top. Now you can withdraw your dose from the vial. Use this solution immediately. If it cannot be used immediately, the solution may be refrigerated for up to 24 hours.

### Measuring the dose of PegIntron from the reconstituted powder for injection

Turn the vial and the syringe upside down in one hand. Be sure the tip of needle is in the PegIntron reconstituted solution. Your other hand will be free to move the plunger. Pull back on the plunger

slowly to draw just more than the dose prescribed by your doctor into the syringe. Hold the syringe with the needle in the vial pointing up, remove the syringe from the long needle leaving the needle in the vial and without touching the tip of the syringe. Take the short needle and place it firmly on to the tip of the syringe. Remove the needle guard from the syringe needle and check for air bubbles in the syringe. If you see any bubbles, pull the plunger slightly back; tap the syringe gently, with the needle pointing upwards, until the bubbles disappear. Push up the plunger slowly back to the correct dose. Replace the needle guard and place the syringe with the needle on a flat surface.

Be sure the solution is at room temperature up to 25°C. If the solution is cold, warm the syringe between your palms. Inspect visually the reconstituted solution prior to administration: do not use if discolouration or particulate matter is present. You are now ready to inject the dose.

#### Injecting the solution

Select the injection site. The best sites for injection are tissues with a layer of fat between skin and muscle: thigh, outer surface of the upper arm (you may need the assistance of another person to use this site), abdomen (except the navel or waistline). If you are exceptionally thin, use only the thigh or outer surface of the arm for injection.

#### **Change your injection site each time.**

Cleanse and disinfect the skin where the injection is to be made. Wait for the area to dry. Remove the needle guard. With one hand, pinch a fold of loose skin. With your other hand, hold the syringe as you would a pencil. Insert the needle into the pinched skin at an angle of approximately 45°. After the needle is in, remove the hand used to pinch the skin and use it to hold the syringe barrel. Pull back the plunger very slightly with one hand. If blood comes into the syringe, the needle has entered a blood vessel. Do not inject into this site; withdraw the needle and repeat the procedure. Inject the solution by pushing the plunger all the way down gently.

Pull the needle straight out of the skin. Press the injection site with a small bandage or sterile gauze if necessary for several seconds. Do not massage the injection site. If there is bleeding, cover with an adhesive bandage.

The vial, ampoule and injection materials intended for single use must be discarded. Dispose of the syringe and needles safely in a closed container.



## PACKAGE LEAFLET

**Read all of this leaflet carefully before you start using this medicine.**

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.

### **In this leaflet:**

1. What PegIntron is and what it is used for
2. Before you use PegIntron
3. How to use PegIntron
4. Possible side effects
5. Storing PegIntron
6. Further information

**PegIntron** 100 micrograms powder and solvent for solution for injection  
peginterferon alfa-2b (conjugation of recombinant interferon alfa-2b with monomethoxy polyethylene glycol)

- The active substance is peginterferon alfa-2b, 100 micrograms/0.5 ml.
- The other ingredients are:  
Powder: dibasic sodium phosphate, monobasic sodium phosphate, sucrose and polysorbate 80;  
Solvent: water for injections 0.7 ml/ampoule.

Marketing Authorisation Holder: SP Europe, 73, rue de Stalle, B-1180 Bruxelles, Belgium

Manufacturer: SP (Brinny) Company, Innishannon, County Cork, Ireland

## **1. WHAT PEGINTRON IS AND WHAT IT IS USED FOR**

The pharmaceutical form is: powder and solvent for solution for injection.

The powder is contained in a 2 ml vial and the solvent is presented in a 2 ml ampoule.

PegIntron 100 micrograms is available in different pack sizes:

- 1 vial of powder for solution for injection and 1 ampoule of solvent for parenteral use;
- 1 vial of powder for solution for injection, 1 ampoule of solvent for parenteral use, 1 injection syringe, 2 injection needles and 1 cleansing swab;
- 4 vials of powder for solution for injection and 4 ampoules of solvent for parenteral use;
- 4 vials of powder for solution for injection, 4 ampoules of solvent for parenteral use, 4 injection syringes, 8 injection needles and 4 cleansing swabs;
- 6 vials of powder for solution for injection and 6 ampoules of solvent for parenteral use;
- 12 vials of powder for solution for injection, 12 ampoules of solvent for parenteral use, 12 injection syringes, 24 injection needles and 12 cleansing swabs.

Not all pack sizes may be marketed.

Interferons modify the response of the body's immune system to help fight infections and severe diseases. PegIntron, which contains an interferon, is used for the treatment of chronic hepatitis C, a viral infection of the liver.

PegIntron is best used for this treatment in combination with ribavirin.

PegIntron is used alone in case of intolerance or contraindication to ribavirin.

## **2. BEFORE YOU USE PEGINTRON**

PegIntron is not recommended for use in patients under the age of 18 years.

### **Do not use PegIntron:**

- If you are hypersensitive (allergic) to peginterferon alfa-2b or any of the other ingredients of PegIntron.
- If you are hypersensitive (allergic) to any interferon.
- If you are pregnant or breast feeding.
- If you have had a severe nervous or mental disorder, especially if you have been very depressed or have thought about suicide, or tried to harm yourself.
- If you have had severe heart problems, or if you have heart disease that has not been well controlled during the past 6 months.
- If you have severe medical conditions that leave you very weak, including severe kidney disease.
- If you have autoimmune hepatitis or any other problem with your immune system; if you are taking medicine that suppresses your immune system (your immune system protects you against infection and some diseases).
- If you have advanced, uncontrolled liver disease (other than hepatitis C).
- If you have thyroid disease that is not well controlled with medicines.
- If you have a condition that causes convulsions (seizures, or “fits”).

### **Take special care with PegIntron:**

- If you develop symptoms of a severe allergic reaction (such as difficulty in breathing, wheezing, or hives) while on this medication, seek medical help immediately.
- If you ever had a heart attack or a heart problem.
- If you have ever been treated for depression or any other nervous or mental disorder.
- If you have had a problem with your liver (other than hepatitis C).
- If you develop symptoms associated with a cold or other respiratory infection, such as fever, cough, or any difficulty in breathing, tell your doctor.
- If you are diabetic, your doctor may ask you to have an eye examination.
- If you have had any serious illness affecting your breathing or your blood.
- If you have psoriasis, it may become worse while you are using PegIntron.
- If you are planning to become pregnant, discuss this with your doctor before starting to use PegIntron.

### **Pregnancy**

Ask your doctor or pharmacist for advice before taking any medicine. Do not use PegIntron during pregnancy. The effect on human pregnancy is not known.

### **Breast-feeding**

Ask your doctor or pharmacist for advice before taking any medicine. It is not known whether this product is present in human milk. Therefore, do not breast-feed an infant if you are taking PegIntron.

### **Driving and using machines:**

Do not drive or operate any tools or machines if you feel tired, sleepy or confused while taking PegIntron.

### **Using other medicines:**

Please inform your doctor or pharmacist if you are taking or have recently taken any other medicines, even those not prescribed.

## **3. HOW TO USE PEGINTRON**

Your doctor has prescribed PegIntron specifically for you and your current condition; do not share this medicine with anyone else.

Your doctor has determined your dose of PegIntron based on your weight. If necessary, the dose may be changed during treatment.

**Combination treatment**

PegIntron, when given with ribavirin capsules, is usually given at a dose of 1.5 microgram/kg once a week.

Ribavirin capsules are taken every day, morning and evening. The number of ribavirin capsules you take depends on your weight.

- If you weigh less than 65 kg, take 2 capsules in the morning and 2 in the evening (total of 800 mg each day).
- If you weigh between 65 and 85 kg, take 2 capsules in the morning and 3 in the evening (total of 1,000 mg each day).
- If you weigh more than 85 kg, take 3 capsules in the morning and 3 in the evening (total 1,200 mg each day).

The combination treatment is continued for at least 6 months, and sometimes for one year.

**PegIntron alone:**

PegIntron, when given alone, is usually given at a dose of 0.5 or 1.0 microgram/kg once a week, for at least 6 months, and possibly for 1 year.

**All patients:**

If you are injecting PegIntron yourself, please be sure that the dose that has been prescribed for you is clearly provided on the package of medicine you receive.

If you have the impression that the effect of PegIntron is too strong or too weak, talk to your doctor or pharmacist.

PegIntron is intended for subcutaneous use. This means that it is injected through a short injection needle into the fatty tissue just under your skin. If you are injecting this medicine yourself, you will be instructed how to prepare and give the injection. Detailed instructions for subcutaneous administration are provided with this leaflet (see How to self-inject PegIntron at the end of the package leaflet).

Prepare the dose just before you intend to inject it and use it immediately. Look carefully at the reconstituted solution prior to administration. Do not use if discolouration of the reconstituted solution is present. Discard any solution that is left in the vial after you give yourself the injection.

Inject PegIntron once each week on the same day. Injecting it at the same time of day each week will help you not to forget to take it.

Use PegIntron exactly as prescribed by your doctor. Do not exceed the recommended dosage, and take it for as long as prescribed.

**If you use more PegIntron than you should:**

Tell your doctor or healthcare professional as soon as possible.

**If you forget to take PegIntron:**

Take the dose as soon as you remember, then continue your treatment as usual.

Do not take a double dose to make up for forgotten individual doses. Contact your doctor or pharmacist if needed.

#### **4. POSSIBLE SIDE EFFECTS**

Like all medicines, PegIntron can have side effects. Although not all of these side effects may occur, they may need medical attention if they do.

Check with your doctor immediately if any of the following side effects occur: chest pain; changes in the way your heart beats; breathing problems, confusion; feeling depressed, wanting to harm yourself, numbness or tingling feeling; trouble sleeping, thinking or concentrating; severe stomach pain; fever or chills beginning after a few weeks of treatment, pain in your lower back or side; problems with your eyesight or hearing; severe bleeding from your nose; your doctor will test your blood to ensure that your white blood cell (cells that fight infection) count and platelets (blood clotting cells) are at acceptable levels.

The most common side effects with the combination of PegIntron and ribavirin capsules are irritation or redness at the site of injection, headache, tired feeling, shaking chills, fever, flu-like symptoms, weakness, loss of weight, nausea, loss of appetite, diarrhoea or loose stools, stomach pain, vomiting, muscle aches, pain in joints and muscles, feeling depressed, irritability, trouble falling asleep or staying asleep, feeling anxious or nervous, difficulty concentrating, mood swings, hair loss, itching, dry skin, sore throat, coughing, difficult breathing, dizziness, virus infection, rash, and dry mouth.

Other common side effects that may occur with combination treatment are increased sweating, chest pain, pain on the right side around your ribs, numbness or tingling feeling, change in thyroid gland activity (which may make you feel tired or, less commonly, energetic), constipation, stomach upset, rapid heart rate, agitation, nervousness, difficult or irregular menstrual period, stuffy or runny nose, change in taste, blurred vision.

Less common are pain at the place of injection, flushing, low or high blood pressure, dry or teary eyes, redness of skin or skin disorder, feeling unwell, feeling faint, confusion, increased or decreased sensitivity to touch, tense muscles, loss of interest in sex, shaky hands, vertigo (spinning feeling), intestinal gas (flatus), bleeding gums or sores in mouth, changes in hearing or ringing in ears, thirst, aggressive behaviour, feeling sleepy, fever blisters, fungal infections, irritation of prostate gland, ear or respiratory infections, sinusitis, abnormal hair texture, sensitivity to sunlight, migraine headache, eye pain or infection, and swollen glands.

Very rarely sarcoidosis (a disease characterised by persistent fever, weight loss, joint pain and swelling, skin lesions and swollen glands) has been reported. Check with your doctor immediately if you have any of these symptoms.

When PegIntron is used alone, some of these effects are less likely to occur, and some have not occurred at all.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

#### **5. STORING PEGINTRON**

Keep out of the reach and sight of children.

Store at 2°C - 8°C (in a refrigerator).

Do not use after the expiry date stated on the carton.

After reconstitution, use the reconstituted solution immediately or within 24 hours when stored at 2°C - 8°C (in a refrigerator).

Do not use PegIntron if you notice discolouration of the powder.

## 6. FURTHER INFORMATION

For any information about this medicinal product, please contact the local representative of the Marketing Authorisation Holder.

### **België/Belgique/Belgien**

Rue de Stalle/Stallestraat 73  
B-1180 Bruxelles/Brussel/Brüssel  
Tél/Tel: + 32-(0)2 370 92 11

### **Luxembourg/Luxemburg**

Rue de Stalle 73  
B-1180 Bruxelles/Brüssel  
Belgique/Belgien  
Tél: + 32-(0)2 370 92 11

### **Danmark**

Hvedemarken 12  
DK-3520 Farum  
Tlf: + 45-44 39 50 00

### **Nederland**

Maarssenbroeksedijk 4  
NL-3542 DN Utrecht  
Tel: + 31-(0)30 240 88 88

### **Deutschland**

Thomas-Dehler-Straße 27  
D-81737 München  
Tel: + 49-(0)89 627 31-0

### **Norge**

Ankerveien 209  
N-1359 Eiksmarka  
Tlf: + 47 67 16 64 50

### **Ελλάδα**

Αγίου Δημητρίου 63  
GR-174 55 Άλμπος  
Τηλ: + 30-(0)10 98 97 300

### **Österreich**

Badener Strasse 23  
A-2514 Traiskirchen  
Tel: + 43-(0)2252 502-0

### **España**

Km. 36, Ctra. Nacional I  
E-28750 San Agustín de Guadalix - Madrid  
Tel: + 34-91 848 85 00

### **Portugal**

Casal do Colaride  
Aqualva  
P-2735 Cacém  
Tel: + 351-21 433 93 00

### **France**

92 rue Baudin  
F-92300 Levallois-Perret  
Tél: + 33-(0)1 41 06 35 00

### **Suomi/Finland**

PL 3/PB 3  
FIN-02201 Espoo/Esbo  
Puh/Tel: + 358-(0)9 613 55 51

### **Ísland**

Lynghálsi 13  
IS-110 Reykjavík  
Tel: + 354 540 80 00

### **Sverige**

Box 27190  
S-10252 Stockholm  
Tel: + 46-(0)8 522 21 500

### **Ireland**

Shire Park  
Welwyn Garden City  
Hertfordshire AL7 1TW - UK  
United Kingdom  
Tel: + 44-(0)1 707 363 636

### **United Kingdom**

Shire Park  
Welwyn Garden City  
Hertfordshire AL7 1TW - UK  
Tel: + 44-(0)1 707 363 636

### **Italia**

Centro Direzionale Milano Due  
Palazzo Borromini  
I-20090 Segrate (Milano)  
Tel: + 39-02 21018.1

**This leaflet was last approved on**

## HOW TO SELF-INJECT PEGINTRON?

The following instructions explain how to inject PegIntron yourself. Please read the instructions carefully and follow them step by step. Your doctor or his/her assistant will instruct you how to self-inject PegIntron. Do not attempt to inject yourself unless you are sure you understand the procedure and requirement of self-injection.

### Preparation

Collect necessary items before you begin:

- a vial of PegIntron powder for injection;
- an ampoule of solvent for PegIntron (water for injections);
- a 1 ml syringe;
- a long needle (for example  $0.8 \times 40$  mm [21 gauge 1.5 inch]) to be used to add water for injections to the PegIntron powder vial;
- a short needle (for example  $0.3 \times 13$  mm [30 gauge 0.5 inch]) for the subcutaneous injection;
- a cleansing swab.

Wash your hands carefully.

### Reconstituting PegIntron powder for injection

Before reconstitution, PegIntron may appear either as a white, tablet-shaped solid that is whole or in pieces, or as a white powder.

Remove the protective cap from the PegIntron vial. Clean the rubber top of the vial with a cleansing swab. You can save the swab to clean the skin area where you will inject the dose. Remove the syringe from the wrapping. Do not touch the tip of the syringe. Take the long needle and place it firmly on to the tip of the syringe. Remove the needle guard without touching the needle and keep the syringe with the needle in your hand. Tap the top of the ampoule of solvent gently to make sure that all the liquid is at the bottom of the ampoule. Break off the top of the ampoule of solvent. Insert the needle in the ampoule of solvent and withdraw the total amount of solvent.

When the total amount of solvent is combined with the full amount of PegIntron powder, the solution will be at the correct concentration to measure your dose (i.e., the labelled amount is contained in 0.5 ml).

A small volume is lost during preparation of PegIntron for injection and when the dose is measured and injected. Therefore, each vial contains an excess amount of solvent and PegIntron powder to ensure delivery of the labelled dose in 0.5 ml of PegIntron, solution for injection.

To prepare the PegIntron solution, insert the needle through the rubber top of the PegIntron vial and gently place the needle tip against the glass wall of the vial without touching the cleaned top of the vial with your hands.

Inject the solvent **SLOWLY**, aiming the stream of liquid at the glass wall of the vial. It is best not to aim the stream directly at the white solid or powder, or to inject the liquid quickly, as this causes a greater amount of bubbles. The solution may appear cloudy or bubbly for a few minutes. This is to be expected and is not cause for concern.

To dissolve the entire contents, swirl the PegIntron vial with a gentle rotary motion leaving the needle and attached syringe in the vial. **Do not shake**, but gently turn the vial upside down until any powder at the top of the vial is dissolved. The contents should now be completely dissolved. Stand the vial upright and let any bubbles present in the solution rise to the top of the solution. Once the solution has settled and all bubbles have risen to the top of the solution, you should have a clear solution with a small ring of tiny bubbles around the top. Now you can withdraw your dose from the vial. Use this solution immediately. If it cannot be used immediately, the solution may be refrigerated for up to 24 hours.

### Measuring the dose of PegIntron from the reconstituted powder for injection

Turn the vial and the syringe upside down in one hand. Be sure the tip of needle is in the PegIntron reconstituted solution. Your other hand will be free to move the plunger. Pull back on the plunger

slowly to draw just more than the dose prescribed by your doctor into the syringe. Hold the syringe with the needle in the vial pointing up, remove the syringe from the long needle leaving the needle in the vial and without touching the tip of the syringe. Take the short needle and place it firmly on to the tip of the syringe. Remove the needle guard from the syringe needle and check for air bubbles in the syringe. If you see any bubbles, pull the plunger slightly back; tap the syringe gently, with the needle pointing upwards, until the bubbles disappear. Push up the plunger slowly back to the correct dose. Replace the needle guard and place the syringe with the needle on a flat surface.

Be sure the solution is at room temperature up to 25°C. If the solution is cold, warm the syringe between your palms. Inspect visually the reconstituted solution prior to administration: do not use if discolouration or particulate matter is present. You are now ready to inject the dose.

#### Injecting the solution

Select the injection site. The best sites for injection are tissues with a layer of fat between skin and muscle: thigh, outer surface of the upper arm (you may need the assistance of another person to use this site), abdomen (except the navel or waistline). If you are exceptionally thin, use only the thigh or outer surface of the arm for injection.

#### **Change your injection site each time.**

Cleanse and disinfect the skin where the injection is to be made. Wait for the area to dry. Remove the needle guard. With one hand, pinch a fold of loose skin. With your other hand, hold the syringe as you would a pencil. Insert the needle into the pinched skin at an angle of approximately 45°. After the needle is in, remove the hand used to pinch the skin and use it to hold the syringe barrel. Pull back the plunger very slightly with one hand. If blood comes into the syringe, the needle has entered a blood vessel. Do not inject into this site; withdraw the needle and repeat the procedure. Inject the solution by pushing the plunger all the way down gently.

Pull the needle straight out of the skin. Press the injection site with a small bandage or sterile gauze if necessary for several seconds. Do not massage the injection site. If there is bleeding, cover with an adhesive bandage.

The vial, ampoule and injection materials intended for single use must be discarded. Dispose of the syringe and needles safely in a closed container.

## PACKAGE LEAFLET

**Read all of this leaflet carefully before you start using this medicine.**

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.

### **In this leaflet:**

1. What PegIntron is and what it is used for
2. Before you use PegIntron
3. How to use PegIntron
4. Possible side effects
5. Storing PegIntron
6. Further information

**PegIntron** 120 micrograms powder and solvent for solution for injection  
peginterferon alfa-2b (conjugation of recombinant interferon alfa-2b with monomethoxy polyethylene glycol)

- The active substance is peginterferon alfa-2b, 120 micrograms/0.5 ml.
- The other ingredients are:  
Powder: dibasic sodium phosphate, monobasic sodium phosphate, sucrose and polysorbate 80;  
Solvent: water for injections 0.7 ml/ampoule.

Marketing Authorisation Holder: SP Europe, 73, rue de Stalle, B-1180 Bruxelles, Belgium

Manufacturer: SP (Brinny) Company, Innishannon, County Cork, Ireland

## **1. WHAT PEGINTRON IS AND WHAT IT IS USED FOR**

The pharmaceutical form is: powder and solvent for solution for injection.

The powder is contained in a 2 ml vial and the solvent is presented in a 2 ml ampoule.

PegIntron 120 micrograms is available in different pack sizes:

- 1 vial of powder for solution for injection and 1 ampoule of solvent for parenteral use;
- 1 vial of powder for solution for injection, 1 ampoule of solvent for parenteral use, 1 injection syringe, 2 injection needles and 1 cleansing swab;
- 4 vials of powder for solution for injection and 4 ampoules of solvent for parenteral use;
- 4 vials of powder for solution for injection, 4 ampoules of solvent for parenteral use, 4 injection syringes, 8 injection needles and 4 cleansing swabs;
- 6 vials of powder for solution for injection and 6 ampoules of solvent for parenteral use;
- 12 vials of powder for solution for injection, 12 ampoules of solvent for parenteral use, 12 injection syringes, 24 injection needles and 12 cleansing swabs.

Not all pack sizes may be marketed.

Interferons modify the response of the body's immune system to help fight infections and severe diseases. PegIntron, which contains an interferon, is used for the treatment of chronic hepatitis C, a viral infection of the liver.

PegIntron is best used for this treatment in combination with ribavirin.

PegIntron is used alone in case of intolerance or contraindication to ribavirin.



## **2. BEFORE YOU USE PEGINTRON**

PegIntron is not recommended for use in patients under the age of 18 years.

### **Do not use PegIntron:**

- If you are hypersensitive (allergic) to peginterferon alfa-2b or any of the other ingredients of PegIntron.
- If you are hypersensitive (allergic) to any interferon.
- If you are pregnant or breast feeding.
- If you have had a severe nervous or mental disorder, especially if you have been very depressed or have thought about suicide, or tried to harm yourself.
- If you have had severe heart problems, or if you have heart disease that has not been well controlled during the past 6 months.
- If you have severe medical conditions that leave you very weak, including severe kidney disease.
- If you have autoimmune hepatitis or any other problem with your immune system; if you are taking medicine that suppresses your immune system (your immune system protects you against infection and some diseases).
- If you have advanced, uncontrolled liver disease (other than hepatitis C).
- If you have thyroid disease that is not well controlled with medicines.
- If you have a condition that causes convulsions (seizures, or “fits”).

### **Take special care with PegIntron:**

- If you develop symptoms of a severe allergic reaction (such as difficulty in breathing, wheezing, or hives) while on this medication, seek medical help immediately.
- If you ever had a heart attack or a heart problem.
- If you have ever been treated for depression or any other nervous or mental disorder.
- If you have had a problem with your liver (other than hepatitis C).
- If you develop symptoms associated with a cold or other respiratory infection, such as fever, cough, or any difficulty in breathing, tell your doctor.
- If you are diabetic, your doctor may ask you to have an eye examination.
- If you have had any serious illness affecting your breathing or your blood.
- If you have psoriasis, it may become worse while you are using PegIntron.
- If you are planning to become pregnant, discuss this with your doctor before starting to use PegIntron.

### **Pregnancy**

Ask your doctor or pharmacist for advice before taking any medicine. Do not use PegIntron during pregnancy. The effect on human pregnancy is not known.

### **Breast-feeding**

Ask your doctor or pharmacist for advice before taking any medicine. It is not known whether this product is present in human milk. Therefore, do not breast-feed an infant if you are taking PegIntron.

### **Driving and using machines:**

Do not drive or operate any tools or machines if you feel tired, sleepy or confused while taking PegIntron.

### **Using other medicines:**

Please inform your doctor or pharmacist if you are taking or have recently taken any other medicines, even those not prescribed.

## **3. HOW TO USE PEGINTRON**

Your doctor has prescribed PegIntron specifically for you and your current condition; do not share this medicine with anyone else.

Your doctor has determined your dose of PegIntron based on your weight. If necessary, the dose may be changed during treatment.

**Combination treatment**

PegIntron, when given with ribavirin capsules, is usually given at a dose of 1.5 microgram/kg once a week.

Ribavirin capsules are taken every day, morning and evening. The number of ribavirin capsules you take depends on your weight.

- If you weigh less than 65 kg, take 2 capsules in the morning and 2 in the evening (total of 800 mg each day).
- If you weigh between 65 and 85 kg, take 2 capsules in the morning and 3 in the evening (total of 1,000 mg each day).
- If you weigh more than 85 kg, take 3 capsules in the morning and 3 in the evening (total 1,200 mg each day).

The combination treatment is continued for at least 6 months, and sometimes for one year.

**PegIntron alone:**

PegIntron, when given alone, is usually given at a dose of 0.5 or 1.0 microgram/kg once a week, for at least 6 months, and possibly for 1 year.

**All patients:**

If you are injecting PegIntron yourself, please be sure that the dose that has been prescribed for you is clearly provided on the package of medicine you receive.

If you have the impression that the effect of PegIntron is too strong or too weak, talk to your doctor or pharmacist.

PegIntron is intended for subcutaneous use. This means that it is injected through a short injection needle into the fatty tissue just under your skin. If you are injecting this medicine yourself, you will be instructed how to prepare and give the injection. Detailed instructions for subcutaneous administration are provided with this leaflet (see How to self-inject PegIntron at the end of the package leaflet).

Prepare the dose just before you intend to inject it and use it immediately. Look carefully at the reconstituted solution prior to administration. Do not use if discolouration of the reconstituted solution is present. Discard any solution that is left in the vial after you give yourself the injection.

Inject PegIntron once each week on the same day. Injecting it at the same time of day each week will help you not to forget to take it.

Use PegIntron exactly as prescribed by your doctor. Do not exceed the recommended dosage, and take it for as long as prescribed.

**If you use more PegIntron than you should:**

Tell your doctor or healthcare professional as soon as possible.

**If you forget to take PegIntron:**

Take the dose as soon as you remember, then continue your treatment as usual.

Do not take a double dose to make up for forgotten individual doses. Contact your doctor or pharmacist if needed.

#### **4. POSSIBLE SIDE EFFECTS**

Like all medicines, PegIntron can have side effects. Although not all of these side effects may occur, they may need medical attention if they do.

Check with your doctor immediately if any of the following side effects occur: chest pain; changes in the way your heart beats; breathing problems, confusion; feeling depressed, wanting to harm yourself, numbness or tingling feeling; trouble sleeping, thinking or concentrating; severe stomach pain; fever or chills beginning after a few weeks of treatment, pain in your lower back or side; problems with your eyesight or hearing; severe bleeding from your nose; your doctor will test your blood to ensure that your white blood cell (cells that fight infection) count and platelets (blood clotting cells) are at acceptable levels.

The most common side effects with the combination of PegIntron and ribavirin capsules are irritation or redness at the site of injection, headache, tired feeling, shaking chills, fever, flu-like symptoms, weakness, loss of weight, nausea, loss of appetite, diarrhoea or loose stools, stomach pain, vomiting, muscle aches, pain in joints and muscles, feeling depressed, irritability, trouble falling asleep or staying asleep, feeling anxious or nervous, difficulty concentrating, mood swings, hair loss, itching, dry skin, sore throat, coughing, difficult breathing, dizziness, virus infection, rash, and dry mouth.

Other common side effects that may occur with combination treatment are increased sweating, chest pain, pain on the right side around your ribs, numbness or tingling feeling, change in thyroid gland activity (which may make you feel tired or, less commonly, energetic), constipation, stomach upset, rapid heart rate, agitation, nervousness, difficult or irregular menstrual period, stuffy or runny nose, change in taste, blurred vision.

Less common are pain at the place of injection, flushing, low or high blood pressure, dry or teary eyes, redness of skin or skin disorder, feeling unwell, feeling faint, confusion, increased or decreased sensitivity to touch, tense muscles, loss of interest in sex, shaky hands, vertigo (spinning feeling), intestinal gas (flatus), bleeding gums or sores in mouth, changes in hearing or ringing in ears, thirst, aggressive behaviour, feeling sleepy, fever blisters, fungal infections, irritation of prostate gland, ear or respiratory infections, sinusitis, abnormal hair texture, sensitivity to sunlight, migraine headache, eye pain or infection, and swollen glands.

Very rarely sarcoidosis (a disease characterised by persistent fever, weight loss, joint pain and swelling, skin lesions and swollen glands) has been reported. Check with your doctor immediately if you have any of these symptoms.

When PegIntron is used alone, some of these effects are less likely to occur, and some have not occurred at all.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

#### **5. STORING PEGINTRON**

Keep out of the reach and sight of children.

Store at 2°C - 8°C (in a refrigerator).

Do not use after the expiry date stated on the carton.

After reconstitution, use the reconstituted solution immediately or within 24 hours when stored at 2°C - 8°C (in a refrigerator).

Do not use PegIntron if you notice discolouration of the powder.

## 6. FURTHER INFORMATION

For any information about this medicinal product, please contact the local representative of the Marketing Authorisation Holder.

### **België/Belgique/Belgien**

Rue de Stalle/Stallestraat 73  
B-1180 Bruxelles/Brussel/Brüssel  
Tél/Tel: + 32-(0)2 370 92 11

### **Luxembourg/Luxemburg**

Rue de Stalle 73  
B-1180 Bruxelles/Brüssel  
Belgique/Belgien  
Tél: + 32-(0)2 370 92 11

### **Danmark**

Hvedemarken 12  
DK-3520 Farum  
Tlf: + 45-44 39 50 00

### **Nederland**

Maarssenbroeksedijk 4  
NL-3542 DN Utrecht  
Tel: + 31-(0)30 240 88 88

### **Deutschland**

Thomas-Dehler-Straße 27  
D-81737 München  
Tel: + 49-(0)89 627 31-0

### **Norge**

Ankerveien 209  
N-1359 Eiksmarka  
Tlf: + 47 67 16 64 50

### **Ελλάδα**

Αγίου Δημητρίου 63  
GR-174 55 Άλιμος  
Τηλ: + 30-(0)10 98 97 300

### **Österreich**

Badener Strasse 23  
A-2514 Traiskirchen  
Tel: + 43-(0)2252 502-0

### **España**

Km. 36, Ctra. Nacional I  
E-28750 San Agustín de Guadalix - Madrid  
Tel: + 34-91 848 85 00

### **Portugal**

Casal do Colaride  
Aqualva  
P-2735 Cacém  
Tel: + 351-21 433 93 00

### **France**

92 rue Baudin  
F-92300 Levallois-Perret  
Tél: + 33-(0)1 41 06 35 00

### **Suomi/Finland**

PL 3/PB 3  
FIN-02201 Espoo/Esbo  
Puh/Tel: + 358-(0)9 613 55 51

### **Ísland**

Lynghálsi 13  
IS-110 Reykjavík  
Tel: + 354 540 80 00

### **Sverige**

Box 27190  
S-10252 Stockholm  
Tel: + 46-(0)8 522 21 500

### **Ireland**

Shire Park  
Welwyn Garden City  
Hertfordshire AL7 1TW - UK  
United Kingdom  
Tel: + 44-(0)1 707 363 636

### **United Kingdom**

Shire Park  
Welwyn Garden City  
Hertfordshire AL7 1TW - UK  
Tel: + 44-(0)1 707 363 636

### **Italia**

Centro Direzionale Milano Due  
Palazzo Borromini  
I-20090 Segrate (Milano)  
Tel: + 39-02 21018.1

**This leaflet was last approved on**

## HOW TO SELF-INJECT PEGINTRON?

The following instructions explain how to inject PegIntron yourself. Please read the instructions carefully and follow them step by step. Your doctor or his/her assistant will instruct you how to self-inject PegIntron. Do not attempt to inject yourself unless you are sure you understand the procedure and requirement of self-injection.

### Preparation

Collect necessary items before you begin:

- a vial of PegIntron powder for injection;
- an ampoule of solvent for PegIntron (water for injections);
- a 1 ml syringe;
- a long needle (for example  $0.8 \times 40$  mm [21 gauge 1.5 inch]) to be used to add water for injections to the PegIntron powder vial;
- a short needle (for example  $0.3 \times 13$  mm [30 gauge 0.5 inch]) for the subcutaneous injection;
- a cleansing swab.

Wash your hands carefully.

### Reconstituting PegIntron powder for injection

Before reconstitution, PegIntron may appear either as a white, tablet-shaped solid that is whole or in pieces, or as a white powder.

Remove the protective cap from the PegIntron vial. Clean the rubber top of the vial with a cleansing swab. You can save the swab to clean the skin area where you will inject the dose. Remove the syringe from the wrapping. Do not touch the tip of the syringe. Take the long needle and place it firmly on to the tip of the syringe. Remove the needle guard without touching the needle and keep the syringe with the needle in your hand. Tap the top of the ampoule of solvent gently to make sure that all the liquid is at the bottom of the ampoule. Break off the top of the ampoule of solvent. Insert the needle in the ampoule of solvent and withdraw the total amount of solvent.

When the total amount of solvent is combined with the full amount of PegIntron powder, the solution will be at the correct concentration to measure your dose (i.e., the labelled amount is contained in 0.5 ml).

A small volume is lost during preparation of PegIntron for injection and when the dose is measured and injected. Therefore, each vial contains an excess amount of solvent and PegIntron powder to ensure delivery of the labelled dose in 0.5 ml of PegIntron, solution for injection.

To prepare the PegIntron solution, insert the needle through the rubber top of the PegIntron vial and gently place the needle tip against the glass wall of the vial without touching the cleaned top of the vial with your hands.

Inject the solvent **SLOWLY**, aiming the stream of liquid at the glass wall of the vial. It is best not to aim the stream directly at the white solid or powder, or to inject the liquid quickly, as this causes a greater amount of bubbles. The solution may appear cloudy or bubbly for a few minutes. This is to be expected and is not cause for concern.

To dissolve the entire contents, swirl the PegIntron vial with a gentle rotary motion leaving the needle and attached syringe in the vial. **Do not shake**, but gently turn the vial upside down until any powder at the top of the vial is dissolved. The contents should now be completely dissolved. Stand the vial upright and let any bubbles present in the solution rise to the top of the solution. Once the solution has settled and all bubbles have risen to the top of the solution, you should have a clear solution with a small ring of tiny bubbles around the top. Now you can withdraw your dose from the vial. Use this solution immediately. If it cannot be used immediately, the solution may be refrigerated for up to 24 hours.

### Measuring the dose of PegIntron from the reconstituted powder for injection

Turn the vial and the syringe upside down in one hand. Be sure the tip of needle is in the PegIntron reconstituted solution. Your other hand will be free to move the plunger. Pull back on the plunger

slowly to draw just more than the dose prescribed by your doctor into the syringe. Hold the syringe with the needle in the vial pointing up, remove the syringe from the long needle leaving the needle in the vial and without touching the tip of the syringe. Take the short needle and place it firmly on to the tip of the syringe. Remove the needle guard from the syringe needle and check for air bubbles in the syringe. If you see any bubbles, pull the plunger slightly back; tap the syringe gently, with the needle pointing upwards, until the bubbles disappear. Push up the plunger slowly back to the correct dose. Replace the needle guard and place the syringe with the needle on a flat surface.

Be sure the solution is at room temperature up to 25°C. If the solution is cold, warm the syringe between your palms. Inspect visually the reconstituted solution prior to administration: do not use if discolouration or particulate matter is present. You are now ready to inject the dose.

#### Injecting the solution

Select the injection site. The best sites for injection are tissues with a layer of fat between skin and muscle: thigh, outer surface of the upper arm (you may need the assistance of another person to use this site), abdomen (except the navel or waistline). If you are exceptionally thin, use only the thigh or outer surface of the arm for injection.

#### **Change your injection site each time.**

Cleanse and disinfect the skin where the injection is to be made. Wait for the area to dry. Remove the needle guard. With one hand, pinch a fold of loose skin. With your other hand, hold the syringe as you would a pencil. Insert the needle into the pinched skin at an angle of approximately 45°. After the needle is in, remove the hand used to pinch the skin and use it to hold the syringe barrel. Pull back the plunger very slightly with one hand. If blood comes into the syringe, the needle has entered a blood vessel. Do not inject into this site; withdraw the needle and repeat the procedure. Inject the solution by pushing the plunger all the way down gently.

Pull the needle straight out of the skin. Press the injection site with a small bandage or sterile gauze if necessary for several seconds. Do not massage the injection site. If there is bleeding, cover with an adhesive bandage.

The vial, ampoule and injection materials intended for single use must be discarded. Dispose of the syringe and needles safely in a closed container.

## PACKAGE LEAFLET

**Read all of this leaflet carefully before you start using this medicine.**

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.

### **In this leaflet:**

1. What PegIntron is and what it is used for
2. Before you use PegIntron
3. How to use PegIntron
4. Possible side effects
5. Storing PegIntron
6. Further information

**PegIntron** 150 micrograms powder and solvent for solution for injection  
peginterferon alfa-2b (conjugation of recombinant interferon alfa-2b with monomethoxy polyethylene glycol)

- The active substance is peginterferon alfa-2b, 150 micrograms/0.5 ml.
- The other ingredients are:  
Powder: dibasic sodium phosphate, monobasic sodium phosphate, sucrose and polysorbate 80;  
Solvent: water for injections 0.7 ml/ampoule.

Marketing Authorisation Holder: SP Europe, 73, rue de Stalle, B-1180 Bruxelles, Belgium

Manufacturer: SP (Brinny) Company, Innishannon, County Cork, Ireland

## **1. WHAT PEGINTRON IS AND WHAT IT IS USED FOR**

The pharmaceutical form is: powder and solvent for solution for injection.

The powder is contained in a 2 ml vial and the solvent is presented in a 2 ml ampoule.

PegIntron 150 micrograms is available in different pack sizes:

- 1 vial of powder for solution for injection and 1 ampoule of solvent for parenteral use;
- 1 vial of powder for solution for injection, 1 ampoule of solvent for parenteral use, 1 injection syringe, 2 injection needles and 1 cleansing swab;
- 4 vials of powder for solution for injection and 4 ampoules of solvent for parenteral use;
- 4 vials of powder for solution for injection, 4 ampoules of solvent for parenteral use, 4 injection syringes, 8 injection needles and 4 cleansing swabs;
- 6 vials of powder for solution for injection and 6 ampoules of solvent for parenteral use;
- 12 vials of powder for solution for injection, 12 ampoules of solvent for parenteral use, 12 injection syringes, 24 injection needles and 12 cleansing swabs.

Not all pack sizes may be marketed.

Interferons modify the response of the body's immune system to help fight infections and severe diseases. PegIntron, which contains an interferon, is used for the treatment of chronic hepatitis C, a viral infection of the liver.

PegIntron is best used for this treatment in combination with ribavirin.

PegIntron is used alone in case of intolerance or contraindication to ribavirin.

## **2. BEFORE YOU USE PEGINTRON**

PegIntron is not recommended for use in patients under the age of 18 years.

### **Do not use PegIntron:**

- If you are hypersensitive (allergic) to peginterferon alfa-2b or any of the other ingredients of PegIntron.
- If you are hypersensitive (allergic) to any interferon.
- If you are pregnant or breast feeding.
- If you have had a severe nervous or mental disorder, especially if you have been very depressed or have thought about suicide, or tried to harm yourself.
- If you have had severe heart problems, or if you have heart disease that has not been well controlled during the past 6 months.
- If you have severe medical conditions that leave you very weak, including severe kidney disease.
- If you have autoimmune hepatitis or any other problem with your immune system; if you are taking medicine that suppresses your immune system (your immune system protects you against infection and some diseases).
- If you have advanced, uncontrolled liver disease (other than hepatitis C).
- If you have thyroid disease that is not well controlled with medicines.
- If you have a condition that causes convulsions (seizures, or “fits”).

### **Take special care with PegIntron:**

- If you develop symptoms of a severe allergic reaction (such as difficulty in breathing, wheezing, or hives) while on this medication, seek medical help immediately.
- If you ever had a heart attack or a heart problem.
- If you have ever been treated for depression or any other nervous or mental disorder.
- If you have had a problem with your liver (other than hepatitis C).
- If you develop symptoms associated with a cold or other respiratory infection, such as fever, cough, or any difficulty in breathing, tell your doctor.
- If you are diabetic, your doctor may ask you to have an eye examination.
- If you have had any serious illness affecting your breathing or your blood.
- If you have psoriasis, it may become worse while you are using PegIntron.
- If you are planning to become pregnant, discuss this with your doctor before starting to use PegIntron.

### **Pregnancy**

Ask your doctor or pharmacist for advice before taking any medicine. Do not use PegIntron during pregnancy. The effect on human pregnancy is not known.

### **Breast-feeding**

Ask your doctor or pharmacist for advice before taking any medicine. It is not known whether this product is present in human milk. Therefore, do not breast-feed an infant if you are taking PegIntron.

### **Driving and using machines:**

Do not drive or operate any tools or machines if you feel tired, sleepy or confused while taking PegIntron.

### **Using other medicines:**

Please inform your doctor or pharmacist if you are taking or have recently taken any other medicines, even those not prescribed.

## **3. HOW TO USE PEGINTRON**

Your doctor has prescribed PegIntron specifically for you and your current condition; do not share this medicine with anyone else.



Your doctor has determined your dose of PegIntron based on your weight. If necessary, the dose may be changed during treatment.

**Combination treatment**

PegIntron, when given with ribavirin capsules, is usually given at a dose of 1.5 microgram/kg once a week.

Ribavirin capsules are taken every day, morning and evening. The number of ribavirin capsules you take depends on your weight.

- If you weigh less than 65 kg, take 2 capsules in the morning and 2 in the evening (total of 800 mg each day).
- If you weigh between 65 and 85 kg, take 2 capsules in the morning and 3 in the evening (total of 1,000 mg each day).
- If you weigh more than 85 kg, take 3 capsules in the morning and 3 in the evening (total 1,200 mg each day).

The combination treatment is continued for at least 6 months, and sometimes for one year.

**PegIntron alone:**

PegIntron, when given alone, is usually given at a dose of 0.5 or 1.0 microgram/kg once a week, for at least 6 months, and possibly for 1 year.

**All patients:**

If you are injecting PegIntron yourself, please be sure that the dose that has been prescribed for you is clearly provided on the package of medicine you receive.

If you have the impression that the effect of PegIntron is too strong or too weak, talk to your doctor or pharmacist.

PegIntron is intended for subcutaneous use. This means that it is injected through a short injection needle into the fatty tissue just under your skin. If you are injecting this medicine yourself, you will be instructed how to prepare and give the injection. Detailed instructions for subcutaneous administration are provided with this leaflet (see How to self-inject PegIntron at the end of the package leaflet).

Prepare the dose just before you intend to inject it and use it immediately. Look carefully at the reconstituted solution prior to administration. Do not use if discolouration of the reconstituted solution is present. Discard any solution that is left in the vial after you give yourself the injection.

Inject PegIntron once each week on the same day. Injecting it at the same time of day each week will help you not to forget to take it.

Use PegIntron exactly as prescribed by your doctor. Do not exceed the recommended dosage, and take it for as long as prescribed.

**If you use more PegIntron than you should:**

Tell your doctor or healthcare professional as soon as possible.

**If you forget to take PegIntron:**

Take the dose as soon as you remember, then continue your treatment as usual.

Do not take a double dose to make up for forgotten individual doses. Contact your doctor or pharmacist if needed.

#### **4. POSSIBLE SIDE EFFECTS**

Like all medicines, PegIntron can have side effects. Although not all of these side effects may occur, they may need medical attention if they do.

Check with your doctor immediately if any of the following side effects occur: chest pain; changes in the way your heart beats; breathing problems, confusion; feeling depressed, wanting to harm yourself, numbness or tingling feeling; trouble sleeping, thinking or concentrating; severe stomach pain; fever or chills beginning after a few weeks of treatment, pain in your lower back or side; problems with your eyesight or hearing; severe bleeding from your nose; your doctor will test your blood to ensure that your white blood cell (cells that fight infection) count and platelets (blood clotting cells) are at acceptable levels.

The most common side effects with the combination of PegIntron and ribavirin capsules are irritation or redness at the site of injection, headache, tired feeling, shaking chills, fever, flu-like symptoms, weakness, loss of weight, nausea, loss of appetite, diarrhoea or loose stools, stomach pain, vomiting, muscle aches, pain in joints and muscles, feeling depressed, irritability, trouble falling asleep or staying asleep, feeling anxious or nervous, difficulty concentrating, mood swings, hair loss, itching, dry skin, sore throat, coughing, difficult breathing, dizziness, virus infection, rash, and dry mouth.

Other common side effects that may occur with combination treatment are increased sweating, chest pain, pain on the right side around your ribs, numbness or tingling feeling, change in thyroid gland activity (which may make you feel tired or, less commonly, energetic), constipation, stomach upset, rapid heart rate, agitation, nervousness, difficult or irregular menstrual period, stuffy or runny nose, change in taste, blurred vision.

Less common are pain at the place of injection, flushing, low or high blood pressure, dry or teary eyes, redness of skin or skin disorder, feeling unwell, feeling faint, confusion, increased or decreased sensitivity to touch, tense muscles, loss of interest in sex, shaky hands, vertigo (spinning feeling), intestinal gas (flatus), bleeding gums or sores in mouth, changes in hearing or ringing in ears, thirst, aggressive behaviour, feeling sleepy, fever blisters, fungal infections, irritation of prostate gland, ear or respiratory infections, sinusitis, abnormal hair texture, sensitivity to sunlight, migraine headache, eye pain or infection, and swollen glands.

Very rarely sarcoidosis (a disease characterised by persistent fever, weight loss, joint pain and swelling, skin lesions and swollen glands) has been reported. Check with your doctor immediately if you have any of these symptoms.

When PegIntron is used alone, some of these effects are less likely to occur, and some have not occurred at all.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

#### **5. STORING PEGINTRON**

Keep out of the reach and sight of children.

Store at 2°C - 8°C (in a refrigerator).

Do not use after the expiry date stated on the carton.

After reconstitution, use the reconstituted solution immediately or within 24 hours when stored at 2°C - 8°C (in a refrigerator).

Do not use PegIntron if you notice discolouration of the powder.

## 6. FURTHER INFORMATION

For any information about this medicinal product, please contact the local representative of the Marketing Authorisation Holder.

### **België/Belgique/Belgien**

Rue de Stalle/Stallestraat 73  
B-1180 Bruxelles/Brussel/Brüssel  
Tél/Tel: + 32-(0)2 370 92 11

### **Luxembourg/Luxemburg**

Rue de Stalle 73  
B-1180 Bruxelles/Brüssel  
Belgique/Belgien  
Tél: + 32-(0)2 370 92 11

### **Danmark**

Hvedemarken 12  
DK-3520 Farum  
Tlf: + 45-44 39 50 00

### **Nederland**

Maarssenbroeksedijk 4  
NL-3542 DN Utrecht  
Tel: + 31-(0)30 240 88 88

### **Deutschland**

Thomas-Dehler-Straße 27  
D-81737 München  
Tel: + 49-(0)89 627 31-0

### **Norge**

Ankerveien 209  
N-1359 Eiksmarka  
Tlf: + 47 67 16 64 50

### **Ελλάδα**

Αγίου Δημητρίου 63  
GR-174 55 Άλιμος  
Τηλ: + 30-(0)10 98 97 300

### **Österreich**

Badener Strasse 23  
A-2514 Traiskirchen  
Tel: + 43-(0)2252 502-0

### **España**

Km. 36, Ctra. Nacional I  
E-28750 San Agustín de Guadalix - Madrid  
Tel: + 34-91 848 85 00

### **Portugal**

Casal do Colaride  
Aqualva  
P-2735 Cacém  
Tel: + 351-21 433 93 00

### **France**

92 rue Baudin  
F-92300 Levallois-Perret  
Tél: + 33-(0)1 41 06 35 00

### **Suomi/Finland**

PL 3/PB 3  
FIN-02201 Espoo/Esbo  
Puh/Tel: + 358-(0)9 613 55 51

### **Ísland**

Lynghálsi 13  
IS-110 Reykjavík  
Tel: + 354 540 80 00

### **Sverige**

Box 27190  
S-10252 Stockholm  
Tel: + 46-(0)8 522 21 500

### **Ireland**

Shire Park  
Welwyn Garden City  
Hertfordshire AL7 1TW - UK  
United Kingdom  
Tel: + 44-(0)1 707 363 636

### **United Kingdom**

Shire Park  
Welwyn Garden City  
Hertfordshire AL7 1TW - UK  
Tel: + 44-(0)1 707 363 636

### **Italia**

Centro Direzionale Milano Due  
Palazzo Borromini  
I-20090 Segrate (Milano)  
Tel: + 39-02 21018.1

**This leaflet was last approved on**

## HOW TO SELF-INJECT PEGINTRON?

The following instructions explain how to inject PegIntron yourself. Please read the instructions carefully and follow them step by step. Your doctor or his/her assistant will instruct you how to self-inject PegIntron. Do not attempt to inject yourself unless you are sure you understand the procedure and requirement of self-injection.

### Preparation

Collect necessary items before you begin:

- a vial of PegIntron powder for injection;
- an ampoule of solvent for PegIntron (water for injections);
- a 1 ml syringe;
- a long needle (for example  $0.8 \times 40$  mm [21 gauge 1.5 inch]) to be used to add water for injections to the PegIntron powder vial;
- a short needle (for example  $0.3 \times 13$  mm [30 gauge 0.5 inch]) for the subcutaneous injection;
- a cleansing swab.

Wash your hands carefully.

### Reconstituting PegIntron powder for injection

Before reconstitution, PegIntron may appear either as a white, tablet-shaped solid that is whole or in pieces, or as a white powder.

Remove the protective cap from the PegIntron vial. Clean the rubber top of the vial with a cleansing swab. You can save the swab to clean the skin area where you will inject the dose. Remove the syringe from the wrapping. Do not touch the tip of the syringe. Take the long needle and place it firmly on to the tip of the syringe. Remove the needle guard without touching the needle and keep the syringe with the needle in your hand. Tap the top of the ampoule of solvent gently to make sure that all the liquid is at the bottom of the ampoule. Break off the top of the ampoule of solvent. Insert the needle in the ampoule of solvent and withdraw the total amount of solvent.

When the total amount of solvent is combined with the full amount of PegIntron powder, the solution will be at the correct concentration to measure your dose (i.e., the labelled amount is contained in 0.5 ml).

A small volume is lost during preparation of PegIntron for injection and when the dose is measured and injected. Therefore, each vial contains an excess amount of solvent and PegIntron powder to ensure delivery of the labelled dose in 0.5 ml of PegIntron, solution for injection.

To prepare the PegIntron solution, insert the needle through the rubber top of the PegIntron vial and gently place the needle tip against the glass wall of the vial without touching the cleaned top of the vial with your hands.

Inject the solvent **SLOWLY**, aiming the stream of liquid at the glass wall of the vial. It is best not to aim the stream directly at the white solid or powder, or to inject the liquid quickly, as this causes a greater amount of bubbles. The solution may appear cloudy or bubbly for a few minutes. This is to be expected and is not cause for concern.

To dissolve the entire contents, swirl the PegIntron vial with a gentle rotary motion leaving the needle and attached syringe in the vial. **Do not shake**, but gently turn the vial upside down until any powder at the top of the vial is dissolved. The contents should now be completely dissolved. Stand the vial upright and let any bubbles present in the solution rise to the top of the solution. Once the solution has settled and all bubbles have risen to the top of the solution, you should have a clear solution with a small ring of tiny bubbles around the top. Now you can withdraw your dose from the vial. Use this solution immediately. If it cannot be used immediately, the solution may be refrigerated for up to 24 hours.

### Measuring the dose of PegIntron from the reconstituted powder for injection

Turn the vial and the syringe upside down in one hand. Be sure the tip of needle is in the PegIntron reconstituted solution. Your other hand will be free to move the plunger. Pull back on the plunger

slowly to draw just more than the dose prescribed by your doctor into the syringe. Hold the syringe with the needle in the vial pointing up, remove the syringe from the long needle leaving the needle in the vial and without touching the tip of the syringe. Take the short needle and place it firmly on to the tip of the syringe. Remove the needle guard from the syringe needle and check for air bubbles in the syringe. If you see any bubbles, pull the plunger slightly back; tap the syringe gently, with the needle pointing upwards, until the bubbles disappear. Push up the plunger slowly back to the correct dose. Replace the needle guard and place the syringe with the needle on a flat surface.

Be sure the solution is at room temperature up to 25°C. If the solution is cold, warm the syringe between your palms. Inspect visually the reconstituted solution prior to administration: do not use if discolouration or particulate matter is present. You are now ready to inject the dose.

#### Injecting the solution

Select the injection site. The best sites for injection are tissues with a layer of fat between skin and muscle: thigh, outer surface of the upper arm (you may need the assistance of another person to use this site), abdomen (except the navel or waistline). If you are exceptionally thin, use only the thigh or outer surface of the arm for injection.

#### **Change your injection site each time.**

Cleanse and disinfect the skin where the injection is to be made. Wait for the area to dry. Remove the needle guard. With one hand, pinch a fold of loose skin. With your other hand, hold the syringe as you would a pencil. Insert the needle into the pinched skin at an angle of approximately 45°. After the needle is in, remove the hand used to pinch the skin and use it to hold the syringe barrel. Pull back the plunger very slightly with one hand. If blood comes into the syringe, the needle has entered a blood vessel. Do not inject into this site; withdraw the needle and repeat the procedure. Inject the solution by pushing the plunger all the way down gently.

Pull the needle straight out of the skin. Press the injection site with a small bandage or sterile gauze if necessary for several seconds. Do not massage the injection site. If there is bleeding, cover with an adhesive bandage.

The vial, ampoule and injection materials intended for single use must be discarded. Dispose of the syringe and needles safely in a closed container.